

## REMARKS

Claims 1-9 are pending in this application.

In the outstanding Official Action, claims 1-9 were subjected to a restriction requirement as well as a specie election.

### *I. Restriction Requirement*

The Examiner has required restriction of claims 1-9 to a single invention under 35 U.S.C. §121 and 372. Claims 1-9 were subjected to a Restriction Requirement as follows:

Group I: Claims 1-8 drawn to a gene panel and a method of producing a gene panel, classified in class 702, subclass 019;

Group II: Claim 9, drawn to a method for screening a drug related to hepatic stellate cell activation, classified in class 702, subclass 019.

Applicants hereby provisionally elect claims 1-8 of Group I, with traverse. Applicants reserve the right to file a divisional application directed to the non-elected subject matter.

Applicants submit that the claims of both Groups I and II, namely claims 1-9, should be examined together because such examination would not present a serious burden.

On page 2 of the Official Action, the Examiner asserts that, "the inventions of Group I and Group II have different effects. Group I is drawn to a gene panel and the related method for producing a gene panel, whereas group II is drawn to a method for screening a drug related to hepatic stellate cell activation...the gene

panel of Group I is not limited to drug screening applications, and therefore can be used for other applications...”

MPEP 803 specifies that restriction/election between two groups of claims is only proper when (1) one group of claims is independent *or* distinct from another group of claims and (2) a “serious burden” exists on the examiner in examining both groups of claims.

The Examiner can show a “serious burden” by establishing one of: the inventions are classified separately; the inventions have been classified together, but it can be shown that each subject has formed a separate subject for inventive effort (can cite patents or show a separate field of search); or the inventions require a separate field of search, that is, it is necessary to search for one subject in a place where no pertinent art for the other subject exists (MPEP 808.02 (c)).

In the present application, the method recited in Claim 9 utilizes the gene panel recited in Claim 1. Therefore, the gene panel of Claims 1 and 9 are both classified in class 702, subclass 019. Consequently, the two Claim groups are not independent from each other. Assuming *arguendo* that the Examiner can establish distinctiveness between the two groups, the Examiner must still establish a “serious burden” resulting from examination of both Groups of Claims. Applicants respectfully submit that no such “serious burden” exists in the present case. Both Groups are directed to a gene panel in the same class as well as subclass.

Further, the method of Claim 9 is limited to the two steps recited: (1) administering a drug; and (2) profiling expressions of genes constituting the gene panel of claim 1. Therefore, Applicants respectfully submit that no additional burden will be endured by examining the claims of Groups I and II together. Accordingly, the Examiner is respectfully requested to withdraw the Restriction Requirement.

**II. Election of Species**

Upon election of Claims 1-8 of Group I, the Examiner has further required that Applicant make the following specie election for purpose of examination:

Specie A: It is recognized that claim 5 limits an expression profile to comprise "at least five kinds of genes," however, for purposes of facilitating search and initial examination, Applicants are required to elect ONE gene from those listed in Tables 1-4.

Applicants hereby provisionally elect, from Specie A, Gene Number 1, listed in Table 1, on page 27 of the specification, with traverse.

The Examiner asserts that the application contains claims directed to patentably distinct species of the claimed invention.

Applicants submit that the Election of Species Requirement is improper because the Examiner has provided no reasoning as to why the asserted species are "distinct." That is, the Examiner has neither suggested an example of a separate utility nor has shown separate classification, status, or field of search (MPEP 808.02 (A-C)).

Two or more species are independent if there is no disclosed relationship between them, i.e., they are unconnected in design, operation, or effect (MPEP 802.01). Two or more species are distinct if, as disclosed, they are related but are capable of separate manufacture, use, or sale, as claimed and are patentable over each other (MPEP 802.01, 806.05).

Because the Examiner is alleging that the species are distinct, the Examiner must show two-way distinctness and reasons for insisting on restriction, i.e., separate classification, status, or field of search. A showing of two-way distinctness requires that a combination as claimed: (1) does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination can be shown to have utility either by itself or in other and different relations.

Where a combination as claimed does not set forth the details of the subcombination as separately claimed and the subcombination has separate utility, the inventions are distinct and the restriction is proper *if* reasons exist for insisting upon the restriction; i.e., separate classification, status, or field of search.

Finally, Applicants note that upon allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141.

In view of the foregoing, Applicants respectfully submit that the search and examination of the claimed species can be made without undue burden. Accordingly, Applicants respectfully request that the Election of Species Requirement be withdrawn.

### CONCLUSION

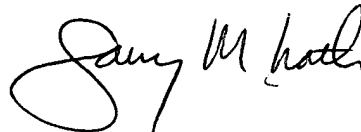
In view of the foregoing, it is submitted that both the Restriction Requirement and the Election of Species Requirement, are improper. Accordingly, the Examiner is respectfully requested to withdraw both requirements, and to examine all of the claims, namely claims 1-9, on the merits.

Applicants submit that the application is in condition for substantive examination. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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